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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,616	01/22/2004	Luisa Hernandez-Ramirez	91349	5023

24628 7590 04/18/2007

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EXAMINER	
HUYNH, CARLIC K	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,616	HERNANDEZ-RAMIREZ ET AL.	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *7-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☒ Claim(s) *1 and 3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-12 are pending in the application, with claims 7-12 having been withdrawn from consideration, in response to the restriction requirement submitted on December 26, 2006. Accordingly, claims 1-6 are being examined on the merits herein.

Election/Restrictions

2. Applicant's election with traverse of Group I, namely claims 1-6, in the reply filed on January 30, 2007 is acknowledged. The traversal is on the ground(s) that the search for the products of Group I would uncover the process of use of Group II. This is not found persuasive because many products can be used with the process of Groups II and thus the search for the products of Group I will not necessarily yield the process of Groups II. Furthermore, if the product claims of Group I are found allowable, then the process claims of Groups II will be rejoined. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104, as per *In re Ochiai.*

Claims 7-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made with traverse in the reply filed on January 30, 2007.

3. The examiner hereby withdrawals the election of species requirement submitted on December 26, 2006.

The restriction requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The Information Disclosure Statement has not been submitted as of this Office Action.

Specification

4. The disclosure is objected to because of the following informalities: typographical errors.

On page 2, line 7, a comma is missing between "parasitic infections" and "urinary or fecal incontinence".

On page 16, line 13, it is a "fluconazole-tinidazole association" as tinidazole is listed as an ingredient in the table associated with example 1.

On page 17, line 4, it is a "fluconazole-tinidazole association" as tinidazole is listed as an ingredient in the table associated with example 2.

On page 17, line 11, it is a "fluconazole-tinidazole association" as tinidazole is listed as an ingredient in the table associated with example 3.

Appropriate correction is required.

5. The abstract of the disclosure is objected to because in line 6, the phrase "either tinidazole is used" is not complete. Another compound should be listed such as secnidazole. Correction is required. See MPEP § 608.01(b).

Claim Objections

6. Claims 1 and 3 are objected to because of the following informalities: typographical errors. Fluconazole is misspelled in claims 1 and 3. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear which compounds are referred to as the "estereoisomer" or "estereoisomeric mixture" in the pharmaceutical composition. Furthermore, the term "acceptable" is not clear.

Examiner notes that it is not clear if "estereoisomer" and "estereoisomeric mixture" has been amended to "stereoisomer" and "stereoisomeric mixture".

It is not clear the unit of weight of tinidzole in the pharmaceutical composition, which is recited as "1000 to less than 2000 tinidazole". To facilitate examination, the weight unit of tinidazole is assumed to be in mg.

8. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear the quantity unit of weight for secnidzole in the pharmaceutical composition, which is recited as "6$ ± 20%". To facilitate examination, the pharmaceutical composition is assumed to be 6% ± 20% by weight of secnidazole.

9. Claim 3 recites the limitation "weight" in claim 2. There is insufficient antecedent basis for this limitation in the claim.

In claim 2, the pharmaceutical composition comprises about 50 to less than 150 mg of fluconazole and 1000 mg to less than 2000 mg of secnidazole. However, in claim 3, which is dependent on claim 2, fluconazole is 75% ± 20% in weight of the total pharmaceutical composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (US 2004/0033968).

Lin et al. teach compositions containing fluconazole, tinidazole, secnidazole, and the like or a combination thereof (page 2, paragraph [0017]).

Lin et al. do not teach the specific amounts of fluconazole and tinidazole or fluconazole and secnidazole in a composition. However, Lin et al. teaches (page 3, Tables 2).

Regarding the about 50 to less than 150 mg fluconazole and from about 1000 to less than 2000 mg tinidazole in the pharmaceutical composition as recited in instant claim 1, Lin et al. teaches compositions contain at least 400 mg of the imidazole anti-fungal compound, which meets the limitations of the instant claims (page 3, Table 2). It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the quantity of the imidazole anti-fungal compounds provided in a composition, according to the guidance set forth in Lin et al., to provide a composition having the desired weight of fluconazole and tinidazole in the pharmaceutical composition. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

11. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (US 2004/0033968) as applied to claims 1-3 above, in view of Eichman (US 5,980,882).

Lin et al. do not teach the pharmaceutical compositions for oral administration, tablet dosage forms, and pharmaceutical vehicles.

Eichman teaches fluconazole, tinidazole and secnidazole can be made into tablets in a drug resin-complex (column 3, line 24; column 9, line 43; column 11, lines 40-41; and column 13, lines 30-33). It is noted that Eichman discloses in the prior art, complexing drugs with a resin oftentimes improves taste and smell, facilitates mass production of the drug, and delays the release of the drug (column 1, lines 27-28, lines 30-31, and lines 50-51).

Eichman further teaches that the tablets contain various pharmaceutically acceptable vehicles such as microcrystalline cellulose, which meets the limitations of the instant claim 6 (column 14, line 21).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the imidazole anti-fungal composition of Lin et al. to contain tablet dosage forms of fluconazole, tinidazole, and seconazole for oral administration because the compounds of Eichman contain tablet dosage forms of fluconazole, tinidazole, and seconazole for oral administration and according to Eichman, fluconazole, tinidazole and seconazole can be made into tablets for oral administration as a drug-resin complex, which is improves the taste of the drug, facilitates mass production of the drug, and delays drug release.

The motivation to combine the compounds of Eichman to the compounds of Lin et al. is that the compounds of Eichman are tablet dosage forms of fluconazole, tinidazole, and seconazole for oral administration in drug-resin complexes that improve the taste of the drug, facilitate mass production of the drug, and delay drug release.

Regarding the about 50 to less than 150 mg fluconazole and from about 1000 to less than 2000 mg of secnidazole in the pharmaceutical composition as recited in instant claim 2, Lin et al. teaches compositions contain at least 400 mg of the imidazole anti-fungal compound (page 3, Tables 2), which meets the limitations of the instant claims (page 3, Tables 2). It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the quantity of the imidazole anti-fungal compounds provided in a composition, according to the guidance set forth in Lin et al., to provide a composition having the desired weight of fluconazole and secnidazole in the pharmaceutical composition. It is noted

that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding % by weight of fluconazole and secnidazole as recited in instant claim 3, Lin et al. teach the compositions contain 16% by weight of the imidazole anti-fungal compound, which meets the limitations of the instant claims (page 3, Table 1). It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the % by weight of the imidazole anti-fungal compounds provided in a composition, according to the guidance set forth in Lin et al., to provide a composition having the desired % by weight of fluconazole and secnidazole in the pharmaceutical composition. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Conclusion

12. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

SUPERVISORY PATENT EXAMINER